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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,987	Applicant(s) PELLERIN ET AL.	
	Examiner MARIA LEAVITT	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11, 14-17 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9, 11, 16 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 10, 14, 17 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 6 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims. Claims 5-11, 14-17 and 19-28 are currently pending. Claims 5, 6, 8, 14, 15, 16, 17 and 19 have been amended, claims 1-4, 12-13 and 18 have been cancelled, and claims 20-28 have been added by Applicants' amendment filed on 09-08-2009.

Newly submitted claim 16 and 28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants originally elected Group V drawn to an isolated nucleic acid of SEQ ID NO: 28, in Applicants' Response filed on 02-24-2009. Currently amended claim 16 is drawn to an isolated nucleic acid with encodes an amino acid sequence according to SEQ ID NO: 27. The isolated nucleic acid as recited in amended claim 16 would have been fully restricted among the isolated nucleic acid sequences if originally presented. Thus currently amended claim 16 clearly belongs to a nonelected invention. Accordingly, **claim 16 is withdrawn** from consideration by the Examiner as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Moreover, new claim 28 is drawn to a method of using a genetically modified yeast cell.

Applicants elected invention drawn to an isolated nucleic acid of SEQ ID NO: 28. New claim 28 is drawn to a method of using a genetically modified yeast cell. Thus new claim 28 clearly belongs to a nonelected group. Accordingly, **claim 28 is withdrawn** from consideration by the Examiner as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 8, 9 and 11 were previously withdrawn for further consideration pursuant to 37

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CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Please note that if an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), **the nonelected invention(s) should be considered for rejoinder**. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). **Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).**

Also note that claims 6 and 15 have been amended to recite “having a sequence according to SEQ ID NO: 28 or SEQ ID NO: 29”. Claims 6 and 15 are examined to the extent that they read on the elected invention, i.e., an isolated nucleic acid having a sequence according to SEQ ID NO: 28.

Response to arguments

At page 8 of the Remarks filed on 09-08-2009, Applicants essentially argue that both the mutated HXT3 gene I (SEQ ID NO: 28) and mutated HXT3 gene II (SEQ ID NO: 29) encode amino acid sequences derived from the wild type HXT3 of amino acid SEQ ID NO: 26 and both sequences contain at least the mutation Ile 209 Val. Moreover, Applicants allege that the species SEQ ID NOS: 28 and 29 belong to the same genus of the elected invention (see claims 5 and 14). The above arguments have been fully considered but deemed unpersuasive.

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In contrast to Applicants' allegation, the isolated nucleic acid sequences of SEQ ID NOS. 28 and 29 were fully restricted as groups and not as species of a genus claim in the requirements for restriction/election mailed on 01-22-2009. The examiner refers Applicants to the reasons of record as set forth at pages 2-4 of the office action filed on 06-03-2009. The restriction requirement was previously made final by the examiner in the office action mailed on 06-03-2009. It is noted that when a final requirement for restriction is made by the examiner, applicant may file a petition under 37 CFR 1.144 for review of the restriction requirement. The propriety of a requirement to restrict, if traversed, is reviewable by petition under 37 CFR 1.144. In re Hengehold, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971).

Therefore, claims 5-7, 10, 14, 15, 17 and 19-27 are currently under examination to which the following grounds of rejection are applicable.

Objections/rejections withdrawn in response to Applicants' arguments or amendments:

Specification Objection

In view of Applicants' amendment of the Specification to provide proper antecedent basis for the claimed subject matter, e.g., mutant HXT3 genes that have the nucleotide sequence according to SEQ ID NO: 28 or 29, and encode the amino acid sequence according to SEQ ID NO: 27 or 30, and furthermore, in view of Applicants' amendment of the Specification to capitalize the trademark Fermichamp®, objection to the specification has been withdrawn.

Claim Rejections - 35 USC § 112- Second Paragraph

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In view of Applicants' amendment of claims 15 and 19, rejection of claims 15-19 under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language, has been withdrawn.

Applicants' arguments are moot in view of the withdrawn rejection.

Claim Rejections - 35 USC § 102(b)

In view of Applicants' amendment of claims 5 and 14 to recite, "having at least a mutation at position Ile 209" and "which nucleic acid comprises a nucleotide sequence encoding the amino acid sequence which is obtained or isolated from SEQ ID NO:26 and having at least a mutation at position Ile 209", respectively, rejection of claim 5, 7, 10, 14 and 16 under **35 U.S.C. §102(b)** as being anticipated by Liang et al., (1998, Molecular and Cellular Biology, pp. 926-935; of record) as evidenced by Ko et al., (1993, Molecular and Cellular Biology, pp. 638-648) has been withdrawn.

Though Liang et al., discloses isolated nucleic acid molecules encoding hexose transporter mutants able to restore glucose-dependent growth to yeast cells including the HXT3-206 mutant, wherein Gln²⁰⁶ →Lys or Arg in TM5, Liang et al., does not teach or suggest of an isolated nucleic acid sequence encoding a mutated HXT3 isolated from SEQ ID No: 26 comprising at least one mutation at Ile 209. Note that amended claims of 09-08-2009 do not place any requirement on at least on amino acid mutation being at position Gln²⁰⁶

Applicants' arguments are moot in view of the withdrawn rejection.

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In view of Applicants' allegations evidencing that Contreras et al., teaches an isolated nucleotide sequence of ID ABQ76349 of 2211 nucleotides in length which has only 99.9% homology to the nucleotide sequence of instantly disclosed SEQ ID NO: 28 of 1704 nucleotides in length because of the difference in one nucleotide in the triplet 1133- 1135 ATT encoding isoleucine, rejection of claims 6 and 15 under **35 U.S.C. §102(b)** as being anticipated by Contreras et al., (WO200264766-A2, Date of publication 22 Aug 2002; Score search results. Application 10582987 and Search Result 20090526_161013_us-10-582-987-28.rng.") has been withdraw.

Applicants' arguments are moot in view of the withdrawn rejection.

Claim Rejections - 35 USC § 112-First paragraph-Scope of Enablement

In view of Applicants' amendment of claim 6, rejection of claim 6 under 35 U.S.C. 112, first paragraph, has been withdrawn.

Applicants' arguments are moot in view of the withdrawn rejection.

Rejections maintained in response to Applicants' arguments or amendments:

Claim Rejections - 35 USC § 103

Claims 14 and 17, 19 remain rejected and claims 5, 7, 10 and 20-27 are newly rejected under 35 USC 103 as being unpatentable over Liang et al., (1998, Molecular and Cellular Biology, pp. 926-935; of record), in view of Liang et al., as evidenced by Ko et al., (1993, Molecular and Cellular Biology, pp. 638-648).

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Liang et al., discloses isolated nucleic acid molecules encoding hexose transporter mutants able to restore glucose-dependent growth to yeast cells containing null alleles of all of the known functional glucose transporter genes upon introduction of the plasmid encoding said hexose transporter mutants (p. 926, col. 2, paragraph 2; p. 928, col. 1, paragraph 1). Note that the sequence of the wild type glucose hexose transporter gene taught by Liang et al., encodes a HXT3 (accession no. L07080) having 100% identity with the HXT3 of SEQ ID No. 26 of the instant invention, as evidenced by the nucleotide and deduced amino acid sequence illustrated in Fig. 2, at page 641 of Ko et al., publication. Accordingly the isolated nucleic acid sequences taught by Liang encode an amino acid sequence that is isolated or obtained from SEQ ID NO:26. Additionally, the HXT3 suppressor mutants disclosed by Liang et al., alter sites that are highly conserved in *S. cerevisiae* at residues that lie within or immediately adjacent to putative membrane-spanning domains (p.928, col. 1, paragraph 2; p. 928, Table 1; p.930, Fig. 3). Indeed, Liang et al., teaches 24 suppressor mutations located adjacent to TM1, TM2, TM4 through TM7, TM10 and TM12 which alter the structure of the putative TMs or the region in the first extracellular loop immediately adjacent to TM1 (p. 928, col. 1, paragraph 2; Table 1). Though Liang et al., does not explicitly teach HXT3 suppressor mutants comprising at least a mutation at position Ile 209 and any additional amino acid mutation selected from the group consisting of Met³²⁴, Leu³⁸⁸, Tyr³⁹⁸, Ile³⁹², Glu⁴¹⁴, Gly⁴¹⁵, Ile⁴⁴⁹ or Leu⁴⁷¹, Liang et al., clearly describes HXT3 mutants with mutations that lie within or immediately adjacent to putative membrane-spanning domains that are critical to mediate glucose transport, for example, mutations that are adjacent to or within the TM5 and disrupt TM5 including Gln²⁰⁶ (e.g., obviating mutations within the TM5 such as Ile 209), mutations that lie within or immediately adjacent to TM7

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and disrupt TM7, e.g., Ser³³⁰, Gln³³², Leu³³⁴ and Gly³³⁶ (e.g., obviating the instantly claimed Met 324 mutation), mutations clustered within TM10 and disrupting TM10 e.g., Ala⁴³⁸, Ala⁴⁴² (e.g., obviating the instantly claimed Ile⁴⁴⁹) and others (See Fig 2 and Table 1 to map location of single amino acid mutations in the twelve-TM model of Hxt3).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made, to generate HX3T mutants employing any combination of conserve residues in *S. cerevisiae* that lie within or immediately adjacent to putative membrane-spanning domains in an attempt to provide an isolated nucleic acid encoding a mutant HX3T with improved glucose transport. At the effective filing date of the present application, the predicted topology of the putative membrane-spanning domains in HXT3 was known in the art as evidenced by the Ho et al., publication. The manipulation of previously identified DNA fragments and cell transformation systems for the design of a novel nucleic acid encoding a mutant HXT3 is within the ordinary level of skill in the art of molecular biology. Moreover, scientific literature abounds with studies of structure alignments and methods of comparing protein structure in order to identify conserved amino acid positions commonly occurring in these protein substructures, thus allowing specific mutations at other locations with minimum distortion to the overall protein structure, scientific literature also proliferate in studies disclosing the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein. The mere combination of mutated residues in *S. cerevisiae* that lie within or immediately adjacent to putative membrane-spanning domains has no patentable significance unless a new and unexpected result is produced. Thus it would have been *prima facie* obvious to one skilled in the art to mutate known amino

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acid residues at locations that are critical for the transport of glucose with a reasonable expectation of success in an attempt to generate a genetically engineered yeast (e.g., *S. cerevisiae*) with enhanced glucose transport capacity, as a person of ordinary skill has good reason to pursue the kwon options within his or her technical grasp. In turn, because the claimed isolated nucleic acid has the properties predicted by the prior art, it would have been obvious to make the claimed mutant HXT3.

Response to Applicants' remarks as they relate to rejection of claims 5, 7, 10, 14, 17 and 19-27 under 35 USC § 103

At page 12 of the remarks filed on 09-08-2009, Applicants essentially argue that: 1) Liang does not teach or suggest mutating an HTX3 gene at least at position Ile 209 to improve fructose transport, 2) Liang is related to glucose transport and would not have been understood to have any relationship to an effect on glucose transport, i.e. mutating the wild type Ile residue improves fructose transport as compared to the wild type, and 3) Liang would suggest making a mutation at Gln 206- or another mutation (s) described in the cited document –expecting to see an effect on glucose transport. The above arguments have been fully considered but deemed unpersuasive.

Regarding 1), in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). None of the references has to teach each and every claim limitation. If they did, this would have been

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anticipation and not an obviousness-type rejection. Therefore, Applicants argument that Liang does not teach mutating an HTX3 gene at least at position Ile 209 is irrelevant.

Regarding 2) and 3), the instant claims are product claims drawn to an isolated nucleic acid encoding an amino acid sequence obtained or isolated from SEQ ID NO: 26 having at least a mutation at position Ile 209. The combination of Liang et al., as evidenced by Ko et al., obviate the instant invention in relation to HX3T mutants with mutations that lie within or immediately adjacent to putative membrane-spanning domains that are critical to mediate glucose transport, for example, mutations that are adjacent or within the TM5 and disrupt TM5 including Gln²⁰⁶, e.g., obviating mutations within the TM5 such as Ile 209. All what is required in the claimed invention is the structure implied by the intended use. Thus in response to applicant's argument that Liang does not teach or suggest "an isolated nucleic acid encoding a mutated HXT3 hexose transporter with an improved capacity to transport fructose as compared to the capacity to transport fructose of a wild-type" as recited in claims 14, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made, to generate HX3T mutants employing any combination of conserve residues in *S. cerevisiae* that lie within or immediately adjacent to putative membrane-spanning domains in an attempt to provide an isolated nucleic acid encoding a mutant HX3T with improved glucose transport. Furthermore, the applicants are reminded that the motivation for combining the teachings of the prior art may be different from applicants' motivation to make the disclosed

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compositions. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The office has provided motivation for making an isolated nucleic acid sequence encoding a mutant HX3T with improved glucose transport comprising at least mutation at Ile 209.

New grounds of objection

Claim Objections

Claims 14 and 15 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 5 and 6. ***This is a new objection necessitated by amendment of the claims in the response filed 09-08-2009.*** Claims 14 and 15 are no different in scope than claims 5 and 6. Both claims 5 and 14 are drawn to an isolated nucleic acid sequence encoding a mutated HXT3 hexose transporter encoding an amino acid sequence obtained from SEQ ID NO: 26 having at least one mutation at position Ile 209. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Additionally, claims 6 and 29 are objected to because Applicants have amended the claims to recite “having a sequence according to SEQ ID NO: 28 or SEQ ID NO: 29”. However, SEQ ID NOS. 28 and 29 were fully restricted originally as groups and not as species of a genus claim. Therefore, the isolated nucleic acid according to SEQ ID NO: 28 or SEQ ID NO: 29 are

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not allowable for rejoinder. Only when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder

Claims 6 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable to the extent that they encompass the isolated nucleic acid sequence of SEQ ID NO: 28 if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 5, 7, 10, 14, 17 and 19-27 are rejected.

Claims 6 and 15 are objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt
Primary Examiner, Art Unit 1633